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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,397	06/25/2003	James A. Peterson	2992.10US04	4852

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,397	<b>Applicant(s)</b> PETERSON ET AL.	
	<b>Examiner</b> Michael G. Mendoza	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 15 August 2005 have been fully considered but they are not persuasive.
2. In response to applicant's argument that the staple is for use in living tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
3. The staple of Morita only needs to be capable of performing the claimed limitation. The staple of Morita only needs to be capable of being deformed into a second deformed position. The limitation of the interior shoulder angle transitioning to between 120-180 degrees does not result in a structural difference from Morita.
4. The staple of Morita teaches all of the structural limitations of the claim i.e., a staple body including a pair of staple arms joined at a shoulder portion by a backspan, an elbow portion, inwardly projecting cleats, and an internal tissue capture zone. The staple of Morita is fully capable of being used in any kind of tissue (living/non-living). Furthermore, the natural tension of tissue (living/non-living) would cause a cut to split. Bringing the split tissue back together would cause a tension pulling on a staple used to bring the cut back together. Furthermore, the Applicant has not specified how much force is required to cause the transition. The forces used for closing tissue in a human would be different for closing tissue in an elephant. The amount of force exerted by

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human tissue (skin) may not be enough transition the staple of Morita. However the force of tissue (skin) in an elephant would, because of the difference in skin tension and thickness.

5. Furthermore, Morita teaches a pair of cleats 17. Because of the angle present by the cleats when the staple is driven into tissue, the staple would spread outwardly making the staple deform into a different position (evidenced by Morehouse US 718649 lines 91-94).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morita JP 06233772.

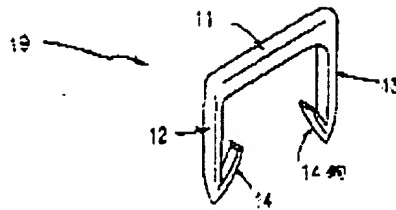
8. Morita teaches a dynamic staple comprising: a staple body including a pair of staple arms operable joined at a shoulder portion by a backspan, each arm further including an elbow portion having an inwardly projecting cleat, the staple arms, the inwardly projecting cleats and the backspan defining an internal tissue capture zone; and each shoulder portion including an interior shoulder angle generally defined by the backspan and the staple arm, the shoulder portion constructed so that the interior shoulder angle is between 70-100 degrees in a first position; and wherein the staple is capable of transitioning between 120-180 degree in a second position when enough

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force is applied to pull the arms apart. It should be noted that Morita fails to teach that the staple is bioabsorbable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the staple of a bioabsorbable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient strength for the intended use of that material. Therefore, it would have been obvious to one having ordinary skill in the art to use a bioabsorbable material for the staple when being used with a living subject to eliminate removal of the staple. Furthermore, it is well known in the art of surgical staples and clips to use a bioabsorbable staple as evidenced by US Patents 4932960, 4994073, 5089009, 5456400.

9. As to claim 11, Morita teaches the staple of claim 10, wherein each elbow portion includes an interior elbow angle generally defined by the staple arm and the cleat, the elbow portion constructed so that the interior elbow angle is less than 70 degrees and is capable of transitioning to a maximum of 90 degrees when enough force is applied to pull the cleat away from the arm.

10. As to claim 12, Morita teaches the staple of claim 10. The staple is capable having the force applied to transition from one angle to the next at any time including the limitation of not less than 12 hours.



### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM

  
GLENN K. DAWSON  
PRIMARY EXAMINER